UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 10
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June 30, 2004

Mr. Jim McKenna
Port of Portland & Co-Chairman, Lower Willamette Group
121 NW Everett
Portland, Oregon 97209

Mr. Robert Wyatt
Northwest Natural & Co-Chairman, Lower Willamette Group
220 Northwest Second Avenue
Portland, Oregon 97209

Re: Portland Harbor Superfund Site; Administrative Order on Consent for Remedial Investigation and Feasibility Study; Docket No. CERCLA-10-2001-0240
Technical Memorandum: Toxicity Reference Value Selection for the Portland Harbor Ecological Risk Assessment

Dear Messrs. Wyatt and McKenna:

EPA has reviewed the Technical Memorandum: Toxicity Reference Value Selection for the Portland Harbor Ecological Risk Assessment. Our review focused on the Toxicity Reference Value (TRV) selection methods and criteria and did not include a detailed, chemical by chemical review of the proposed TRVs. Because of the complexity of the TRV selection process, EPA proposes developing provisional TRVs to be used in the Preliminary Risk Evaluation (PRE). The PRE, in conjunction with other information, can be used to narrow the suite of contaminants and receptors for which a detailed review of the literature is required to develop final TRVs.

As you are aware, we have a meeting scheduled for July 6, 2004 to discuss the TRV Technical Memorandum. We would like to discuss the concept of provisional TRVs with you at that time and agree on a path forward for revising the TRV Technical Memorandum based on the attached comments.

If you have any questions, please call Chip Humphrey at (503) 326-2678 or Eric Blischke (503) 326-4006. All legal inquiries should be directed to Lori Cora at (206) 553-1115.

Sincerely,

Chip Humphrey
Eric Blischke
Remedial Project Managers

cc: John Crellin, ATSDR
Helen Hillman, NOAA
Ted Buerger, US Fish and Wildlife Service
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Valerie Lee, Environment International
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EPA Comments on TRV Selection Technical Memorandum
June 30, 2004

The Toxicity Reference Value Selection for the Portland Harbor Ecological Risk Assessment Technical Memorandum (TRV TM) represents a reasonable first effort to derive toxicity reference values (TRVs) for a wide range of contaminants. For most contaminants, the literature review was thorough. The document is well-written and it is clear from the text how the proposed numbers were developed. The complete lists of screened and evaluated papers presented in the appendices are particularly helpful and were much appreciated by EPA and its partner reviewers. Although we have numerous comments, we want to commend the Lower Willamette Group (LWG) for organizing a bewildering amount of information into a clear and concise format.

This review focused on the TRV selection methods and criteria. With the exception of a partial review of the fish TRVs presented in Section 3, a chemical-by-chemical review for each receptor class was not completed. Once we have reached agreement on the selection criteria a more complete review can be completed. Furthermore, EPA believes the TRV values should not be finalized at this stage of the process. Neither the Lower Willamette Group nor the agencies should spend additional time and resources refining TRVs that may not be useful. EPA and its partner reviewers put considerable effort into reviewing this tech memo, but we were not able to review papers for all of the contaminants addressed. Rather than try to review everything, EPA prefers to focus on review papers for those TRVs that will make a difference in the outcome of the risk assessment.

EPA proposes revising the TRV TM based on the comments presented below with the goal of developing provisional TRVs. The provisional TRVs should be appropriately conservative and used in the Preliminary Risk Evaluation (PRE) to help narrow the list of contaminants that will drive risk. In deciding which contaminants to carry forward into the baseline risk assessment, several factors should be considered, including the degree of exceedance of the provisional TRVs, the frequency of exceedance, and whether the substance is elevated above background concentrations and hence is subject to potential remedial action. Before the baseline risk assessment, EPA and the Lower Willamette Group should re-visit those TRVs that are likely to drive risk and result in cleanup action.

General Comments

Evaluation Forms:

The evaluation forms documenting bird, mammal and fish TRV selection should be submitted to EPA as an appendix to the TRV TM. This will facilitate review by allowing EPA to evaluate study specific assumptions and calculations in order to pull relevant information from these studies into calculated TRVs.

Reliance on Dietary-Based Studies

The technical memo developed TRVs primarily based on dietary-based laboratory studies. Dietary studies should not by default represent the preferred method of dosing when choosing TRVs. Problems with dietary based lab toxicity studies are primarily due to the difficulty in ensuring that the test subject has been dosed correctly or has accepted the vehicle (i.e., food) used for dosing. This may be accounted for if the researcher weighs the spilled or discarded food during the experiment. Studies should be rejected if the discarded/spilled food was not accounted for. In addition, growth of test subjects must be accounted for and compared to controls, or a study should be rejected. Problems associated with dietary studies include, but are not limited to, the following sources of variation, which may lead to inaccurate does response curves:

1. The test chemical can escape from the food "phase" after the food is dosed prior to consumption by the test animal. This is generally ignored or may be assumed negligible depending on the carrier, but still is a source of variation, and can still result in the subject not receiving the intended dose.
2. The test subjects may be able to detect the chemical or carrier in food and limit eating or consume food at slower rates than control subjects, and therefore will not receive the intended dose.
3. Test subjects may not be able to directly detect the chemical in food but will undergo chemical-induced anorexia and limit eating food compared to control subjects (this is fairly common in organophosphorous/carbamate pesticide studies) and therefore will not receive the intended dose.

Thus, dietary food studies can result in under- or overestimation of NOAELs/LOAELs.
In contrast, studies conducted by dosing subjects via oral gavage or inter-muscular, inter–peritoneal, or egg injection can be more accurate because a known amount of chemical is delivered into the subject without rejection, and the chemical will have a more exact, translatable response exhibited by the test subject. The dose may not be as representative of how an organism receives a dose in the field, but the delivery method can be translated to a valid tissue effect residue value (provided the researcher analyzes tissues during or after the study). In fact, given all the sources of uncontrollable variability associated with food/dose delivery, the dietary pathway studies might be considered on par with field studies in the hierarchical consideration of toxicity studies considered to derive TRVs. Thus, TRV development should include dietary studies, field studies, and injection studies to best represent exposure to ecological receptors at the Portland Harbor site.

Where sufficient literature is available, the TRV TM should identify both TRVs based on tissue concentrations and TRVs based on dietary exposure. The two values should be used in a weight of evidence approach in the risk assessment. This would provide a more robust basis for decision making. For most substances, there are probably more studies that measured (only) the dose for fish than there are studies that measured tissue concentrations.

Use of Field Studies:

The TRV TM states that most field studies were excluded from development of TRVs. This is not an acceptable approach. Many field studies help support laboratory studies and field studies represent a realistic exposure scenario. Field studies are a key component of ecotoxicological assessments and must be included in TRV development, especially when determining egg TRVs for birds. It is likely that many field studies will be applicable to developing TRVs for fish, and field studies are available on listed species or closely related species whereas lab studies may be less available. It is unacceptable to rely on laboratory studies alone for development of TRVs. As stated in U.S. Environmental Protection Agency (EPA) (2003) guidance "Avian effects data are available from both laboratory toxicity tests and field studies of birds at contaminated sites. Each type of study has advantages and disadvantages…However, laboratory studies are always subject to the criticism that conditions or the mode of exposure are unrealistic. Field studies are inherently realistic, but are inevitably uncontrolled, unrandomized and, at best, imperfectly replicated. Hence, the laboratory and field results represent alternative estimates of the effects of exposure to dioxin-like compounds, each with strengths and weaknesses." Thus, as supported by EPA guidance, the LWG should consider field studies as well as lab studies to obtain a better representation of effects thresholds to fish and wildlife at the Portland Harbor site. This is especially true when establishing TRVs for dioxins-like compounds, DDE, and PCBs.

Lack of TRVs for Certain Contaminants:

It was not possible to develop TRVs for all the contaminants of interest, due to a lack of literature. The document should identify a process for handling these contaminants. Comparison to "background" concentrations is one possible mechanism. Lab studies or other information may be required to develop toxicity information for suspect contaminants that are significantly elevated above "background."

Use of Safety Factors:

Many of the TRVs proposed are based on mortality tests. For example, the tissue-based TRV for endrin in bivalves is the concentration reported to cause 90% mortality. The concentration reported in this study is certainly not a threshold for adverse effects, and should not be used as the lowest observed effect concentration. Values based on mortality should be adjusted downwards using a safety factor if no studies with sublethal endpoints are available. Similarly, many of the proposed values are based on short-term tests, with an acute exposure of 96 hours or less. These studies are not appropriate to used in predicting effects over a long period, or over the entire life cycle of an organism. Chronic exposure studies should be used whenever they are available. Where chronic exposure studies are not available, the values should be adjusted by use of a safety factor.

Assessing Quality of Study:

The reasonableness of the derived TRVs should be discussed more explicitly in the TRV TM.

Comparison among the TRVs selected for similar and related substances might help determine whether the selected values are consistent. Where multiple studies used similar dosing levels, it would be helpful to know how the selected value compares with the values from the other studies. For example, is the selected number within a factor of two or three, or several orders of magnitude below similar studies? How did the quality of the selected study compare with the quality of similar studies? Are the TRVs lower than concentrations in fish tissue from non-impacted sites? For some chemical classes, good information is available on relative toxicity; are the numbers consistent with our knowledge of relative toxicity? Selecting the lowest or highest value found in the literature provides consistency of process, but may not result in numbers in which we feel confident. The goal of the TRV TM is to develop the best values available. As a result, a sense of the level of uncertainty around the numbers is required. An assessment of uncertainty should be include in an uncertainty section at the end of each chapter. The text from these sections could be carried forward into the risk assessment documents to inform future readers about the utility of the values.

Assessing Direct Exposure to Contaminated Media:

Fish and other receptors may be exposed to contaminants present in sediment and/or surface water through direct contact. The tech memo should include TRVs for estimating risks from direct exposure to contaminated sediments and direct exposure to contaminants in the water column. This evaluation should include an evaluation of applicable or relevant and appropriate water quality criteria. If these values will be developed at a later date, this process should be explained in the Introduction.

Contaminants of Interest:

The contaminants of interest for fish and invertebrates are based only on those chemicals measured in tissue collected during Round 1 of the RI/FS. For wildlife, both contaminants measured in tissue and contaminants measured in sediment were included in the contaminants of interest list. Bottom-feeding fish and benthic invertebrates can ingest sediment as they eat. As a result, historic sediment data and information on chemicals that could have been released from upland facilities should be included in the TRV development process.

Salmonids and Other Migratory Fish Species:

Salmon should not be addressed separately from other fish. If there were sufficient literature to derive separate, protective TRVs for salmon, the proposed approach would be acceptable. However, the results of the literature search make it clear that this is not the case. The proposed TRVs for many of the contaminants are ten, thirty, even a hundred times higher for salmon than for other fish. EPA does not believe that salmon are significantly less sensitive than other fish. The differences are an artifact of the (few) salmon studies available.

Although it is unclear whether Chinook salmon or lamprey spawn in the ISA, reproductive

endpoints are relevant and should be considered in the TRV selection process. Chemical contaminants that are accumulated in body tissue during feeding or presence in the ISA may directly affect reproductive success. Chemical contaminants that bioaccumulate may result in a decreased fitness of spawning fish as well as decreased fitness of eggs and offspring. Additionally, exposure to metabolizable chemical contaminants during upstream migration can affect reproductive success by modifying behavior or fitness of eggs and offspring.

Treatment of Summed Chemicals:

The TRV TM does not explain clearly how summed chemicals vs. individual chemicals or congeners in the exposure term will be compared to TRVs. For example, are total PCBs to be calculated and then compared to the lowest aroclor TRV? EPA recommends developing TRVs for total PCBs as well as for individual Aroclors. With respect to chlordane, will various forms of chlordane be summed, or will the risk assessment be performed for individual forms only? If a TRV is based on total chlordane, but it is compared to a single form, risk could be underestimated.

Need for Individual Fish Tissue Data:

Because the tissue samples consist primarily of composite samples, it may be difficult to assess risk to fish with residues near the TRV concentration. Fish respond to their own internal dose of a contaminant, not to a mean concentration from a number of pooled individuals. If some of the TRVs become risk drivers and are used to establish cleanup requirements, an additional round of tissue sampling that measures contaminants in individual fish, focused only on the species and contaminants that could drive cleanup, may be necessary.

Whole Body vs. Other Tissue Types:

The selection criteria for TRVs only considers whole body tissue concentrations and states that studies that measure chemical concentrations in specific tissue types such as liver, fat or muscle will be excluded from consideration. If studies focusing on certain chemical contaminants are limited, this rule may exclude all information regarding toxicity effects of such chemicals. Where whole-body information is unavailable, it may be possible use conversion factors to obtain a whole-body concentration value. Additionally, where specific tissue concentrations are directly linked to the selected endpoints, such data should be considered in developing TRVs. The paper selection criteria should be expanded to include tissue concentrations for other tissue types such as fillet, liver or egg/embryo, especially when citations are limited for a specific chemical. Conversions between tissue types can be made to get to an assumed whole body concentration, as was done for the Sheboygan River and Harbor Aquatic Risk Assessment, 1998. For conversion factors, see Nimi 1983 and Russell et al. 1999.

Search Criteria:

The quality of the TRVs selected is dependent on the literature review and screening process. It is important that the procedure for selecting TRVs be presented in a clear manner demonstrating how the literature search was conducted and how the information was screened. All databases searched should be identified (currently only some of the literature sources are listed), a summary of the studies that were screened out and the screening criteria used should be presented, and a complete list of search terms used in the screening process should be listed. This information should be included to help ensure that the literature review and screening process was complete and that relevant studies were not inadvertently excluded.

Hierarchy of TRV Selection Factors:

r how much weight the individual selection criteria had in calculating a TRV. For example, when several different selection criteria came into play, what was the hierarchy, or dominant process that drove TRV selection.

y Factors/NOECs and LOECs:

an be derived from LOAELs using uncertainty factors and vice versa. Uncertainty factors should be used in order to quantitatively evaluate risk. The TRV TM should incorporate this approach when appropriate.

t TRV process is based on selecting the lowest LOEC or if none is available the highest NOEC. There is no justification for setting the TRVs to the lowest LOEC or highest NOEC in all cases. TRVs should be based on a weight of evidence approach to selecting the most appropriate values.

where a study provides both the lowest observed effects concentration and a no observed effects concentration, we would prefer to use both values, rather than pick a different study for the no observed effects concentration.

taminant Specific Conversion Factors:

e clear how conversion factors were used in TRV development. For example, they were used in some studies, but not others (e.g., the use of a 7.02 conversion factor for bis(2-ethylhexyl)phthalate).

Exposure to Chemical Mixtures:
The TRV TM states that studies that examine fish exposed to mixtures other than certain congeners were not considered. This exclusion rule may result in less conservative TRVs that are not representative of actual conditions. Exposure to multiple chemicals is likely to result in more adverse effects than exposure to individual chemicals. This information is directly relevant to determining TRVs. This exclusion rule should be modified to include studies that examine mixtures of chemicals similar to the selected COIs.

Studies Unrelated to Growth, Reproduction or Mortality:

TM excluded studies that did not relate to growth, reproduction, or mortality. This rule is too stringent as chronic effects may relate to the selected endpoints. For instance, exposure to certain chemicals can decrease behavioral responses affecting prey capture rates or predator evasion resulting in mortality of the contaminated fish. These studies should not automatically be excluded and relevant data should be used in developing TRVs.

tiveness:

Section 2.3.2 states "studies were reviewed for methods to ensure that conditions in the study were adequately representative of exposure conditions in the ISA and that TRVs were appropriately derived." This section lacks a thorough discussion of what factors are representative of ISA exposure conditions. All factors used in this process should be clearly identified and presented with the weight assigned to each factor.

List Rejected Studies in Main Text:

Rejected studies should be listed in parenthesis in the text of the appropriate section in the memo. Although this information is presented in Appendix B, it would help the reviewer to cite the rejected studies in the main text where they are first mentioned.

Specific Comments

Section 1.0 - Introduction, Page 1:

The tech memo should include at least a few paragraphs in the Introduction that explain how the proposed values will be used in the overall risk assessment. An understanding of how exposure will be determined and how the values will be used in the preliminary and baseline risk evaluations will aid review of the proposed TRVs.

The TRV TM defines TRVs as the minimum concentration that represents some level of documented risk (associated with effects). However, some TRVs were based on NOAELs, which are defined as the level associated with no effects. The introductory sentence should be clarified to reflect this concept.

Figure 1, Page 4: Figure describes the literature review process. The figure should include a pathway to address the possible removal of particular contaminants due to insufficient literature. Risk to fish and invertebrates from these excluded contaminants would need to be assessed via some other mechanism, perhaps by comparison to "background" concentrations in tissue.

Section 2.0 - TRV Selection Methods, Page 3:

TRVs for Fish: The first sentence states "COIs for fish are those chemicals detected in fish tissue samples…." COIs should include those chemicals that are found in tissues as well as

compounds such as PAHs which fish can be exposed to and harmed by, but are metabolized and not commonly found in tissues. The first sentence should be modified to reflect the inclusion of metabolized COIs.

TRVs for Wildlife: TRVs for wildlife should be reported as dietary doses and as concentrations in eggs for bird receptors. The egg concentration approach should be added to the paragraph.

Section 2.1 - Identification of Chemicals of Interest, Page 6, First Bullet: TBT should be evaluated in fish as a COI in the preliminary screening. Invertebrates may be more sensitive to TBT, but the sensitive types of invertebrates may not be present or have limited distribution in the harbor (i.e., invertebrates may fall out of the risk equation for reasons other than sensitivity), and so we need to be sure that other organisms are protected and evaluated in the TBT risk assessment. TBT may elicit adverse effects on other invertebrates, and potentially fish and wildlife as well.

Section 2.1 - Identifying Chemicals of Interest, Page 6 Second Bullet: No screening of contaminants has occurred yet. For example, it is unclear whether it is appropriate to screen out aluminum. Contaminant screening should take place only in the context of the overall Portland Harbor RI/FS.

Section 2.2 - Endpoints Evaluated, Page 6: Endpoints should not be limited to growth, reproduction, and survival. Behavioral endpoints that could effect survival (e.g. reduced foraging efficiency, reduced predator avoidance) should also be included. Also include other endpoints that could affect survival, especially endpoints from early life stage tests.

Section 2.3, TRV Selection for Fish, Page 7: For chemicals detected in fish tissue, but are also metabolized (e.g., PAHs and certain metals), the dietary approach should be used in conjunction with a tissue residue evaluation.

Section 2.3.2, Page 9, TRV Selection:

It is unclear why studies where fish were dosed by gavage were not used. The dose is known in these studies with certainty and the resulting adverse effect is measured.

Taxonomic similarity should be considered, but if a TRV is not available in this family, other fish studies (from different studies) should take precedent over the use of surrogate chemical information. The limited number of studies available for those in the family Salmonidae may actually result in a higher TRV than one derived from other families. This could actually result in assuming that fish from the family Salmonidae are actually much less sensitive than other fish.

Section 2.3.3 and Section 2.4.4, NOAEL and LOAEL Selection: The highest NOAEL should not be the dominant selection criteria at this stage. The PRE will involve a screening process, and therefore the TRVs should be appropriately conservative at this point. NOAELs and

LOAELs are relatively arbitrary in most studies, and are a function of the concentration gradient selected by the investigator. As a result, these NOAELs and LOAELs may not accurately reflect the dose response of the test organism and the contaminant. Therefore, NOAELs and LOAELs should instead be selected on the merits of the study. At this stage, the focus should be on the lowest NOAEL until the baseline risk assessment, or a range of NOAELs and LOAELs should be reported for comparison to environmental concentrations.

Section 2.3.1 – Literature search and review, Page 7: Specific information regarding the databases search and the keywords used should be provided. This information could be included in a fairly simple table and would expedite determining other possible sources of information.

Section 2.3.1 Prioritization of relevant studies for TRV selection, Pages 8 - 9:

- Reporting dietary concentrations should not necessarily be a requirement for exclusion.
- All forms of the chemical should be considered – not just the test chemical in the same form that is at the site.
- The most sensitive life stage should be selected for the TRV.
- Requiring a comparison to control will eliminate a lot of field studies, which may provide the most relevant information.
- Studies that include exposures to a contaminant mixture should not be automatically eliminated.
- TRVs in fish eggs can be used if fish egg concentrations can be estimated from sediment concentrations at the site.
- Fish egg to whole body relations should be made to help assess survival of eggs and fry for resident fish in the harbor.
- Bioaccumulation studies may be useful in confirming NOAELs or when building a weight of evidence to support TRVs, and therefore some studies might be helpful and should not be broadly excluded.
- Studies reporting specific organ or tissue concentrations should not be eliminated a priori. As mentioned above, endpoints in addition to growth, reproduction and survival should be reviewed. EPA acknowledges that enzymatic and biochemical endpoints are hard to interpret, however; other endpoints such as behavior should be included, especially if they can impact growth, survival or reproduction. In addition to behavior, include other endpoints potentially affecting survival, reproduction and growth.

- Studies that reported effects based on concentrations in eggs should not be eliminated a priori. Dose to egg and subsequent effects to early life stage fish are critical and need to be considered. The TRV calculated for Bis (2-ethylhexyl) phthalate converted concentrations in sac fry to an adult concentration. A similar approach can be used for converting egg concentrations to adult concentrations (Russell et al. 1999).

- Field studies that include a reference should be reviewed. Field collected reference fish may introduce some uncertainty to a study, but they also bring real benefits. For example, field-collected reference fish have lipid concentrations similar to field fish, unlike lab-reared fish that may have higher lipid concentrations.

Section 2.3.2 - TRV Selection Criteria, Page 9: Field studies should be included when developing TRVs for listed salmonids, as lab studies on listed species may not be available. Data from field studies on a listed species would be preferable to lab data on a different species.

Section 2.3.3 - NOEC and LOEC Selection, Page 10: The discussion of DDT implies that data for the toxicity of 4,4'-DDT only was not used. This exclusion seems unnecessary and the data would provide a good comparison to the results for the mixtures. For dioxins and PCB congeners, the citation for the WHO TEFs should be included.

Section 2.4.1 - Literature search and review, Excluded studies:

- Exposure routes other than oral exposure should be considered.

- Those that didn't have a control group should be considered – this would eliminate many field studies.

- For studies where only an abstract could be obtained, additional effort may be required to track down the study if it is determined relevant to the TRV development process.

Section 2.4.1 - Literature search and review - General database search, Page 11:

Ingestion techniques for delivery of chemical into eggs and derivation of egg TRVs should be included here. Guidance from the U.S. Environmental Protection Agency (2003) states that for evaluating risk of dioxin-like compounds in birds "The contaminant composition of eggs, from either injection or maternal contribution, is the appropriate exposure metric" and "Measures of effect may be used with measures of exposure derived either by measuring concentrations in eggs at a contaminated site or by modeling egg concentrations to characterize avian risks from a single dioxin-like chemical or a mixture of such chemicals."

Immunoresponse, biochemical, and histopathological changes measured in a study should be

included in the TRV if these changes can be linked to reproduction, survival, and growth.

Section 2.4.1 - Literature search and review - Identification of studies for TRV selection, Page 12:

Studies that exposed test organisms to more than one dioxin-like compound should be considered as well, because the mode of action for dioxin-like chemicals is the same.

Review studies should be valid sources of NOAELs/LOAELs and should be included in the data gathering and review process. Some review studies evaluate existing lab and field data on a bird species, and then extrapolate to an endangered species or species that has not been tested in the lab. Thus, a review study that established NOAELs or LOAELs should be considered in the TRV approach.

As stated in earlier comments, field studies should be included in TRV development (especially for birds and mammals), as they may be the best source available for estimating risks and threshold values to sensitive species rather than interpreting lab data on a surrogate species.

Section 2.4.2 - NOAEL and LOAEL Calculations, Page 13:

The NOAEL and LOAEL calculations should be presented for each species, and a table should be included that lists all the body weights and ingestion rates used for each receptor. Allometric scaling equations that are appropriate for individual species should be utilized and all equations used should be presented. For birds, the generic "all bird" equation should not be used where the species, or a good surrogate, has been studied (e.g., common sandpiper in Table 1 or Nagy 2001). For mammals, it is unclear what equation was used ("all laboratory mammals, EPA 1993 – this equation could not be located).

Section 2.4.3 - TRV selection criteria - Page 14:

The exclusion of Japanese quail and chickens based on egg productivity (due to their unnaturally high egg-laying rates) should be clarified. Were studies on these birds excluded for all reproductive endpoints, or just egg laying? These test organisms are selected for reproductive studies because they are so prolific, and sample sizes are improved. Therefore, data on these species should not be excluded for all reproductive endpoints.

The last paragraph states that all life stages were considered for bird and mammal TRVs by considering effects to the developing embryo. Which reproductive endpoints were used for each chemical, and how was maternal transfer into eggs evaluated based on dietary studies? Additional information should be provided to clarify these issues. In addition, key studies deriving effect levels on birds and mink were excluded in the TRV approach because they were field studies or exhibited more realistic dosing regimes than in laboratory studies. As stated

earlier, effects to the developing embryo in birds needs to be assessed using effect levels derived for eggs (including field studies) and reproduction in mink should include field studies where their feeding supply is derived from a contaminated source, especially when the contaminants in the feeding sources have been characterized.

Section 3.1.1 - 2,3,7,8-TCDD, Page 16 - 17: Review paper on rainbow trout by Giesy et al. 2002. The following studies can also be included: Elonen et al. 1998, Guiney et al 1996, Johnson et al 1998, Prince and Cooper (1995), Spehar et al. (1997), Spitsbergen et al. (1991), Walker et al. (1991, 1992), Chen and Cooper (1999).

Section 3.1.2 - PCB Aroclors, Pages 17 - 18: The following studies should be included in the TRV evaluation table:

- Ankley et al. 1991, which evaluates eggs and fillet of Chinook salmon and relative hatching success.

- Berlin et al. 1981- This paper was reviewed, but discounted in Table B-1 due to lack of background concentration / elevated mortality of lake trout at the start of experiment. This study should be included in the TRV evaluation with a NOEC/control of 0.3ppm and a LOEL of 1.53 ug/g due to significantly increased mortality from day 97 to 176.

- Fisher et al 1994. Atlantic salmon exposed to Aroclor mixture of 1016, 1221, 1254, 1260 with respect to hatching success, survival, growth and behavior modification- background of 0.33 ppm

- Freeman and Idler 1975, Guieny et al. 1996, Walker et al. 1991, 1992 and 1994- Each were initially discounted due to only the egg concentration being reported.

- Hendricks J, et al. 1981, which evaluates dietary exposure of rainbow trout to Aroclor 1254 - egg effect concentration of 1.64 ppm (control 0.47ppm).

- McCarthy et al. 2003.

- Wintermyer and Cooper. 2003 Which evaluates dioxin/furan and PCB bioaccumulation in transplanted eastern oysters.

Section 3.1.3 - Mercury, Page 18:

- Use the Matta et al. 2001 NOEC and LOEC for all fish species.

- The Rodgers and Beamish (1982) study should not be used because dosing started with 25 ppm mercury, no intermediate doses were given between the control and 25 ppm. Therefore, a LOEC cannot be determined from this study. The Matta et al. (2001) paper used three dosing intervals below the 25 ppm concentration and measured an effect with a 2 ppm dose. The Matta et al. (2001) paper better characterizes the threshold for response and is therefore a better approximation of a low effect tissue residue. Because the endpoint is not reproduction, it can be applied to salmon.

Section 3.1.4 – Pesticides, Pages 18 - 23:

Aldrin: Here is a good reason for an uncertainty section at the end of each chapter (see our general comment, above). For aldrin, the uncertainty section should state that the TRV is from a single study, with no effects observed, a single exposure dose, and that the method of exposure was injection.

Chlordane: Parrish found effects in acute toxicity tests at water concentrations of 5 ug/L for pinfish. However, Cardwell et al. (1977) measured reproductive effects in chronic tests using brook trout at water concentrations of 0.3 ug/L chlordane. While tissue residues were not measured in the brook trout study, use of a safety factor to extrapolate to a chronic exposure and sublethal endpoint is appropriate. (If the pinfish BCF of 3000 is used with the effect concentration of 0.3 ug/L, a tissue residue of 0.9 ppm is calculated, or if a safety factor of 10 is used, the TRV becomes 1.6 ppm).

Total chlordane TRVs should not be compared to each isomer concentration, but rather the total chlordane in the fish (sum of isomers) should be compared to the total chlordane TRV.

DDT: Include studies such as Berlin et al. (1981) that used field-collected fish tested in the lab. Also review Butler (1969).

The Allison et al. (1964) study reports a range of effect concentrations over the duration of the study. EPA recommends using a value of 1.1 ppm from this paper to be consistent with the overall goal of selecting a minimum threshold concentration. The 3.0 ppm concentration used by Windward was measured in fish after the mortality effect was noted.

p.20 Dieldrin: Also calculate TRV using egg concentration (similar to method used for bis (2-ethylhexyl phthalate) from rejected Smith and Cole (1973) study.

Review Gakstattter and Weiss (1967) study because behavior and overall condition are relevant endpoints.

Section 3.1.5 - SVOCs, Page 23:

Bis(2-ethylhexyl)phthalate: Review Chikae et al. (2004) and Kim et al. (2002) papers to see if tissue residues are reported. In addition, the excluded study is not listed in Table B-1, please add it.

Section 3.2, Fish Diet Based TRVs: As stated previously, If metals were detected in fish tissue, tissue residue TRVs should also be developed.

Section 3.2.1 - Metals, Pages 24 - 27:

Cadmium: The Handy (1993) paper requires further review. The author saw 38% mortality between days 3 and 23 of the exposure period, at a concentration of 100 mg/g.

Section 3.2.2 - Total and individual PAHs, Page 27: It is inappropriate to select a NOEC from the Palm et al. (2003) study at this point, especially since a key measurement in the Palm et al. (2003) study was immunosuppresion. Other studies from the NOAA Fisheries Science Center have indicated immunosuppresion at lower levels for PAHs. Further discussion of the merits of these studies is required before selecting a NOEC for PAHs.

Section 4.0 - Wildlife TRV Selection Summary, Page 29: As stated earlier, TRVs for birds for dioxin-like chemicals, DDE, PCBs, and other bioaccumulative chemicals should be based on the most sensitive endpoint, the developing embryos. Therefore, NOAELs/LOAELs should be selected based on egg concentrations. The dietary pathway need not be addressed unless modeling contaminant concentrations from the diet to the egg, resulting in an estimated egg concentration that can be compared to an egg NOAEL/LOAEL.

Section 4.1 - Bird TRV Selection, Page 29: This whole section needs to be revised to include field studies, which will likely dramatically change the proposed TRV values. Therefore, EPA will not be providing comments on individual TRVs selected for birds because the process for selection should be changed. The process for selecting TRV values for birds should include field study evaluations and lab studies using egg injection techniques. Also, the process should evaluate estimated egg NOAELs/LOAELs for bioaccumulative compounds derived from previous field or lab studies, or from review papers which derive conservative TRVs for listed or sensitive species based on data from surrogate species. A species sensitivity distribution using both field and lab data as outlined by the U.S. Environmental Protection Agency (2003) could be used to investigate a range of TRVs and select a conservative value for a species in question. EPA will provide a list of references to consider, as well as a process to include egg

NOAELs/LOAELs in the TRV approach for birds, at a later date. At a minimum, egg values should be used to assess risk for the following chemicals: dioxin-like chemicals including planar PCBs, DDE, and possibly mercury.

Section 4.2 - Mammal TRV Selection, Page 42: As stated earlier, field studies should be considered when deriving TRVs for mammals. EPA will provide a list of references that include field studies that should be considered when deriving TRVs for mink and river otter. Therefore, the proposed TRVs for mammals proposed in this section should not be approved at this time.

Section 5.1: Introduction, Page 58: The TRV TM should note that only two clam samples were collected during the Round 1 sampling event. These samples are not sufficient to determine risk to the bivalve population. If this approach is to be used in any sort of quantitative fashion, additional samples will be needed.

Section 5.2.3.1 - Literature search and review, Page 59: The TRV TM states that literature retrieved was limited to studies reporting whole-body concentrations. Studies that included only the edible muscle, which is most of the bivalve, should be included.

Section 5.2.3.2 - Decapod and Crustacean TRV selection criteria, Page 60:

Same comments apply to invertebrate literature screening as mentioned above for fish (e.g., expand endpoints beyond reproduction, growth, and survival).

Zebra mussel papers should not excluded a priori. If the studies are more recent and focus on more sensitive endpoints, they should be reviewed. If the TRVs from the Zebra mussel studies are lower than other species, then use the lowest TRV number.

Section 5.3.5 - Pesticides, Pages 62 - 65:

Chlordanes: When no statistics were done to identify a significant effect, the lowest concentration showing a difference should be used. It is not clear why 0.71 ppm was selected as the LOEC instead of 0.49 ppm.

Endosulfan: If the effect concentration is lower than the detection limit in tissue then the detection limit can be used. Using a less sensitive species that had a higher tissue concentration is inconsistent with the goal of identifying minimum effect concentrations. Confirm the reasonableness of the pink shrimp concentration by comparison to background concentrations from clean areas.

Table 1, Fish and Wildlife COIs:

It is unclear how COIs were selected for this table. A table with the fish tissue data would be

useful.

PCBs: Aroclor 1242 and Aroclor 1254 should be included as COIs.

PAHs: Are those not listed as “Fish COIs” just for tissue residue TRVs? These should be included as metabolized COIs.

Table 1 should note whether the contaminant is a fish tissue or dietary COI.

Table 1 does not list many of the PAHs as COIs for fish, yet they are used in the dosing studies review.

Attachment A
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